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FILING DATE: *March 31, 2004*
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Certified by

Jon W. Dudas

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PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

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INVENTOR(S)		
Given Name (first and middle [if any])	Family Name or Surname	Residence (City and either State or Foreign Country)
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Additional inventors are being named on the _____ *separately numbered sheets attached hereto*

TITLE OF THE INVENTION (500 characters max)

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ENCLOSED APPLICATION PARTS *(check all that apply)*

☑ Specification *Number of Pages* 15 ☐ CD(s), Number _____

☑ Drawing(s) *Number of Sheets* 1 ☐ Other (specify) _____

☐ Application Data Sheet. See 37 CFR 1.76

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Respectfully submitted,

SIGNATURE Charles T. Joyner

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Date MAR 31, 2004

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Docket Number: 1001-04

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☑ Applicant claims small entity status. See 37 CFR 1.27

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Complete if Known	
Application Number	
Filing Date	March 31, 2004
First Named Inventor	Soltero
Examiner Name	
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FEE CALCULATION

1. BASIC FILING FEE

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
1001	770	2001	385	Utility filing fee	
1002	340	2002	170	Design filing fee	
1003	530	2003	265	Plant filing fee	
1004	770	2004	385	Reissue filing fee	
1005	160	2005	80	Provisional filing fee	80.00

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2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

		Extra Claims		Fee from below		Fee Paid
Total Claims		-20** =		X	=	
Independent Claims		- 3** =		X	=	
Multiple Dependent					=	

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description
1202	18	2202	9	Claims in excess of 20
1201	86	2201	43	Independent claims in excess of 3
1203	290	2203	145	Multiple dependent claim, if not paid
1204	86	2204	43	** Reissue independent claims over original patent
1205	18	2205	9	** Reissue claims in excess of 20 and over original patent

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FEE CALCULATION (continued)

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1051	130	2051	65	Surcharge - late filing fee or oath	
1052	50	2052	25	Surcharge - late provisional filing fee or cover sheet	
1053	130	1053	130	Non-English specification	
1812	2,520	1812	2,520	For filing a request for *ex parte* reexamination	
1804	920*	1804	920*	Requesting publication of SIR prior to Examiner action	
1805	1,840*	1805	1,840*	Requesting publication of SIR after Examiner action	
1251	110	2251	55	Extension for reply within first month	
1252	420	2252	210	Extension for reply within second month	
1253	950	2253	475	Extension for reply within third month	
1254	1,480	2254	740	Extension for reply within fourth month	
1255	2,010	2255	1,005	Extension for reply within fifth month	
1401	330	2401	165	Notice of Appeal	
1402	330	2402	165	Filing a brief in support of an appeal	
1403	290	2403	145	Request for oral hearing	
1451	1,510	1451	1,510	Petition to institute a public use proceeding	
1452	110	2452	55	Petition to revive - unavoidable	
1453	1,330	2453	665	Petition to revive - unintentional	
1501	1,330	2501	665	Utility issue fee (or reissue)	
1502	480	2502	240	Design issue fee	
1503	640	2503	320	Plant issue fee	
1460	130	1460	130	Petitions to the Commissioner	
1807	50	1807	50	Processing fee under 37 CFR 1.17(q)	
1806	180	1806	180	Submission of Information Disclosure Stmt	
8021	40	8021	40	Recording each patent assignment per property (times number of properties)	
1809	770	2809	385	Filing a submission after final rejection (37 CFR 1.129(a))	
1810	770	2810	385	For each additional invention to be examined (37 CFR 1.129(b))	
1801	770	2801	385	Request for Continued Examination (RCE)	
1802	900	1802	900	Request for expedited examination of a design application	

Other fee (specify) _____

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SUBMITTED BY				(Complete *(if applicable)*)	
Name (Print/Type)	Charles T. Joyner	*Registration No. (Attorney/Agent)*	30,466	*Telephone*	(919)4799330
Signature				*Date*	March 31, 2004

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PROVISIONAL APPLICATION

Under CFR 1.53(c)

Method for Administering Medicaments to Dysphagic Subjects

FIELD OF THE INVENTION

The present invention provides a variably thickened pharmaceutical composition for supplying oral medicaments to a patient demonstrating or at risk for abnormalities in swallowing.

BACKGROUND OF THE INVENTION

A normal human swallow can be separated into four semi-distinct phases according to Dr. Aviv at the Voice and Swallowing Center, Columbia University (http://www.voiceandswallowing.com/swall_norm.htm) . Any one or more of these stages in the swallowing process can become impaired and result in abnormalities in the human swallow, a condition called dysphagia. A spectrum of very different medical conditions, both physical and neurological in nature, can alter normal swallowing. For example, acute dysphagia may be the result of inflammatory conditions such as pharyngitis, tonsillitis, or aphthous ulceration of the mouth.

A number of approaches are conventionally employed to enable administration of oral medicaments to a subject following a diagnosis of dysphagia. In general, oral solid dosage forms such as tablets, capsules, pills, and powders are not easily taken by a dysphagic patient, and a liquid or syrup formulation of the prescribed medicament may be substituted, if available. This approach has been described by Dessibourg and Gachoud, for example, as a means for administering the medications levodopa and benserazide in the treatment of patients with Parkinson disease. [C.A. Dessibourg and J.P. Gachoud, *Schweiz. Rundsch. Med.*

Prax. 84(43), 1235-1238, *1995*.] Frequently, however, no liquid dosage form of a medicament is commercially available, or the liquid medicament formulation may cause choking, difficulty in swallowing, or regurgitation, or may have an undesirable or bitter taste or after-taste, poor dispensability or instability.

As an alternative, a person providing care to a dysphagic person often attempts to transfer a medicament to a thickened drink or soft food immediately prior to administration. A tablet containing a drug may be partially crushed, for example, and the fragments added to a thickened or viscous liquid or soft food. Likewise, the contents of a capsule may be emptied into a thickened liquid or soft food and dispersed by stirring. Frequently, the fragments of the drug dosage form are not uniformly dispersed, and portions of the original dose remain in the mixing container. Further, the presence of the drug-containing particles in the food or liquid may elicit an abnormal swallowing response, leading to coughing, regurgitation, or aspiration. When this occurs, the net result is a failure to deliver the requisite dose of the medicament to the subject and an enhanced risk of aspiration and its undesirable consequences.

Yet another conventional treatment for patients who have trouble swallowing involves the use of enteral feeding tubes through which a liquid formulation of a drug may be administered. Skilled care-givers must insert the enteral feeding tube. Moreover, use of an enteral feeding tube requires that a liquid formulation of the drug be available and that the drug is compatible with the tube material.

U.S. Patent No. 6,531,114 teaches methods and delivery vehicles, i.e., chewing gum dosage forms, for delivering a medicament. Chewing creates a pressure within the oral cavity of the individual to force the drug directly into the systemic system of that individual through the oral mucosa of the oral cavity via the buccal or sublingual absorption routes. However, a subject having dysphagia may lack the cognitive skills or oral motor skills to derive benefit from prolonged chewing

of chewing gum dosage forms or may suffer coughing, discomfort, choking, and pain by attempting to swallow the chewing gum dosage form.

U.S. Patent No. 5,932,235 teaches a jellied medical composition for oral administration, which is easily taken by patients of advanced age or patients with dysphagia. U.S. Patents No. 5,558,880 and 5,648,093 claim a fast dissolving, solid dosage form defined by a matrix containing gelatin, pectin and/or soy fiber protein and one or more amino acids having from about 2 to 12 carbon atoms. The dosage form is formed by subjecting a matrix material solution to lyophilization or solid-state dissolution.

There has been a long-felt and unmet need for a method for the oral administration of medicaments to dysphagic patients and those at risk for swallowing abnormalities, as well as methods for the preparation of compositions that will enable oral administration of medicaments to this population of people. The present invention addresses this need.

SUMMARY OF THE INVENTION

The present invention provides a solid dosage form that facilitates swallowing comprising a hydrated polymeric gelatinous matrix, one or more active ingredients and optionally one or more excipients.

The second embodiment of the invention is a method for administering to a patient a solid dosage form that facilitates swallowing comprising a hydrated polymeric matrix, one or more active ingredients and optionally one or more excipients without water or other fluids needed to facilitate swallowing.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1. Side view of the dosage form of the present invention.

Fig. 2. End view of the dosage form.

DETAILED DESCRIPTION

The dosage form of the present invention, because of the gelatinous consistency of its hydrated polymeric matrix, is softly resilient, yet is appropriately firm to facilitate swallowing and passage down the esophagus without hesitation, coughing, pain, and regurgitation. It is cohesive in the mouth, and passes through the throat smoothly when swallowed. Accordingly, it is particularly suitable for medication delivery for patients with dysphagia or swallowing abnormalities,

The dosage form has ingestion qualities and textural properties allowing it to be readily positioned in the mouth by, *e.g.*, pressing with the tongue, without chewing, and smoothly passes through the throat. It promotes salivation, which further facilitates swallowing.

The essential components in the dosage form are an active, *i.e.* biologically active, ingredient and a hydrated polymeric material, but one or more secondary ingredients, *i.e.* excipients, may be optionally added. Preferably, all non-active ingredient components are food grade or "generally recognized as safe" (GRAS) by those skilled in the art of pharmaceutical preparations. The dosage form can be made into a variety of shapes. However, the preferred shape is a cylinder with a rounded end as depicted in Fig. 1 and Fig. 2.

The active ingredient may include pharmaceuticals, vitamins, minerals, and diagnostics. Examples of pharmaceutical agents that may be incorporated in the gelatinous composition are acetaminophen, captopril, diltiazem, nifedipine, dicyclomine, alprazolam, amitriptyline, clomipramine, propranolol hydrochloride, labetalol, allopurinol, metformin, atenolol, potassium chloride, lithium, levothyroxine sodium, ibuprofen, estrogen, and acetyl salicylic acid. However, substantially any pharmaceutical agent may be used as the active ingredient, either by adding the

active agent to the mixture to be jellied or by adding solutions, emulsions, liposomes, or complexes of the active agent to the mixture to be jellied. One or more excipients such as preservatives, flavors, antioxidants, surfactants, sweeteners, or colorings may also be incorporated into the formulation.

Hydrateable polymeric materials suitable for preparation of the matrix in the present dosage form include materials derived from animal or vegetable proteins, such as the gelatins, dextrins and soy, wheat and psyllium (see proteins); gums such as acacia, guar, agar, and xanthan; polysaccharides; alginates; carboxymethylcelluloses; carrageenans; dextrans; pectins; synthetic polymers such as polyvinylpyrrolidone and polyacrylic acid polymers such as carboxyvinylpolymers and carbomers; and polypeptide/protein or polysaccharide complexes such as gelatin-acacia complexes. Preferred matrix forming agents include pharmaceutical grade gelatins, pectins (nonhydrolyzed, partially hydrolyzed or hydrolyzed), and hydrolyzed celluloses, either alone or in combination.

Process for preparation:

Typically, a hydrateable polymeric matrix material is mixed with water to form a suspension, into which the active ingredient(s) and optionally one or more excipients are blended. The mixture is then processed to induce gelling, *e.g.*, heating. The mixture is then cast into molds wherein it gels. Alternatively, the mixture is allowed to cool and the gel is extruded as the dosage form from the mold. Those knowledgeable in the pharmaceutical arts will recognize that a variety of both natural and synthetic polymers are useful for forming the gelatinous matrix.

Besides the chemical nature of polymer and solvent, the three most important factors causing phase separation, precipitation, and gelation of polymer solutions are temperature, concentration, and molecular weight. Lower temperatures, higher concentrations, and higher molecular weights promote gelling and produce stronger gels. (Remington 308)

For a typical gelatin, 10% solutions acquire yield values and begin to gel at about 25 °C; 20% solutions at about 30 °C; and 30% solutions at about 32 °C. The gelation is reversible; the gels liquefy when heated above these temperatures. Gelation is rarely observed above 34 °C regardless of concentration, so that gelatin solutions do not gel at 37 °C. The gelation temperature or gel point is highest at the isoelectric point, where the attachment between different chains by coulombic attraction or ionic bonds between carboxylate groups and alkylammonium, guanidinium or imidazolium groups is most extensive.

The gelation temperature or the melting point of the gel depends more strongly on temperature and concentration than on pH. The combination of an acid pH considerably below the isoelectric point and a temperature of 37 °C completely prevents the gelation of gelatin solutions. Agar and pectic acid solutions set to gels at only a few percent of solids. Unlike most water-soluble polymers, methylcellulose, hydroxypropylcellulose, and polyethylene oxide are more soluble in cold that in hot water. Their solutions therefore tend to gel on heating.

Gelatin can have two isoelectric points, depending on the method of preparation. So-called Type A gelatin, derived from an acid-treated precursor, has an isoelectric point of between pH 7 and 9. Type B gelatin, obtained from an alkali-treated precursor, has an isoelectric point of approximately pH 5. Type A gelatin acts best as an emulsifier around pH 3, where it is positively charged. On the other hand, Type B gelatin is best around pH 8, where it is negatively charged. Both Type A and Type B gelatin can be used in this invention. To avoid an incompatibility, all emulsifying agents should carry the same charge.

The gelation temperature or melting point of gelatin-water systems is in the range of 20 to 40 °C. It increases with increasing gelatin content and with increasing gelatin molecular weight, as does the solution viscosity above the gelation temperature and the gel rigidity below it. While the modulus and the ultimate strength of aqueous gels increase with increasing gelatin content, the

elongation at break is not much affected. Gel strength and rigidity are highest at the isoelectric point, where cross-linking by salt bridges is most extensive. While typical aqueous gelatin gels contain 20 to 45% solids, pectin and agar form strong gels at room temperature which contain only 1 to 4% solids.

The dosage form of the present invention can include medications to treat a variety of diseases. Examples of such diseases include systemic diseases such as hypertension, within day precision disorder, heart diseases (e.g., cardiac hypertrophy, acute heart failure, congestive heart failure, chronic heart failure, cardiomyopathy, angina pectoris, myocarditis, arrhythmia, tachycardia, myocardial infarction, etc.), cerebrovascular disorder (e.g., asymptomatic cerebrovascular disorder, transient cerebral ischemia, cerebral apoplexy, cerebrovascular dementia, hypertensive cerebropathy, etc.), cerebral edema, cerebral circulatory disorder, recurrence and sequela of cerebrovascular disorder (neurotic symptom, psychic symptom, subjective symptom, disorder in daily living activities, etc.), ischemic peripheral circulatory disorder, myocardial ischemia, venous insufficiency, progression of cardiac insufficiency after myocardial infarction, diabetes mellitus, diabetic complications (diabetic retinopathy, diabetic nephropathy, diabetic neuropathy, etc.), renal diseases (nephritis, glomerulonephritis, glomerulosclerosis, renal failure, thrombotic vasculopathy, complications of dialysis, organ disorder including nephropathy by radiation damage, etc.) arteriosclerosis including atherosclerosis (aneurysm, coronary arteriosclerosis, cerebral arteriosclerosis, peripheral arteriosclerosis, etc.), vascular hypertrophy, vascular hypertrophy or obliteration and organ failure after intervention (percutaneous transluminal coronary angioplasty, stenting, coronary angioscopy, intravascular ultrasound, douche thrombolytic therapy, etc.), vascular re-obliteration and restenosis after bypass, polycythemia, hypertension, organ failure and vascular hypertrophy after transplantation, rejection after transplantation, ocular diseases (glaucoma, ocular hypertension, etc.), thrombosis, multiple organ failure, endothelial dysfunction, hypertensive tinnitus, other cardiovascular diseases (deep vein thrombosis, obstructive impairment, arteriosclerosis obliteran, obliterative thromboangiitis,

transient cerebral circulation disorder, Raynaud's disease, Berger disease, etc.), metabolic and/or nutritional disorder (obesity, hyperlipemia, hypercholesterolemia, diabetes mellitus, impaired glucose tolerance, hyperuricacidemia, hyperkalemia, hypernatremia, etc.), nerve degeneration diseases (Alzheimer's disease, Parkinson's disease, amyotrophic lateral sclerosis, AIDS related cerebral symptom, etc.), central nervous system disorder (cerebral hemorrhage, cerebral infarct, their sequela, complication, head injury, spinal injury, cerebral edema, sensory malfunction, sensory functional disorder, autonomic nervous system disorder, autonomic nervous system malfunction, multiple sclerosis, etc.), dementia, defects of memory, disorder of consciousness, amnesia, anxiety symptom, catatonic symptom, disconform mental state, psychopathy, (depression, epilepsy, alcoholism, etc.), inflammatory diseases (diabetic complication such as retinopathy, nephropathy, neuropathy great vessel dysfunction; arthritis such as rheumatoid arthritis, osteoarthritis, rheumatoid myelitis, periostitis; inflammation after operation and injury; remission of swelling; pharyngitis; cystitis; pneumonia; atopic dermatitis; inflammatory intestinal diseases such as Crohn's disease, ulcerative colitis; meningitis, inflammatory ocular disease; inflammatory pulmonary diseases such as pneumonia, pulmonary silicosis, pulmonary sarcoidosis, pulmonary tuberculosis, etc.), allergic diseases (allergic coryza, conjunctivitis, gastrointestinal allergy, pollinosis, anaphylaxis, etc.), chronic obstructive pulmonary disease, interstitial pneumonia, pneumocytis carinni pneumonia, collagen diseases (e.g., systemic lupus erythematosus, scleroderma, polyarteritis, etc.), hepatic diseases (chronic hepatitis, hepatic cirrhosis, etc.), portal hypertension, digestive system disorder (gastritis, gastric ulcer, stomach cancer, stomach disorder after operation, dyspepsia, esophageal ulcer, pancreatitis, colon polyp, cholelithiasis, hemorrhoidal disease, etc.), blood and/or myelopoietic diseases (erythrocytosis, vascular purpura, autoimmune hemolytic anemia, disseminated intravascular coagulation, multiple myelopathy, etc.), bone diseases (fracture, refracture, osteoporosis, osteomalacia, bone Behcet's disease, sclerosing myelitis, rheumatoid arthritis, osteoarthrosis of the knee and joint tissue distruction owing to similar diseases and disorder, etc.), solid ulcer, ulcer [malignant melanoma, malignant lymphoma,

cancer of digestive organs (e.g., cancer of stomach, intestine, etc.)], cancer and cachexia following cencer, metastasis cancer, endocrinopathy (Addison's disease, Cushing's syndrome, pheochromocytoma, primary aldosteronism and the like), Creutzfeldt-Jakob disease, urinary organ and/or male genital diseases (cystitis, prostatic hypertrophy, prostatic cancer, sex infectious disease, etc.), female disorder (climacteric disorder, gestosis, endometriosis, hysteromyoma, ovarian disease, breast disease, sex infectious disease, etc.), diseases and disorder related to environment and occupational factors (radiation hazard, hazard by ultraviolet, infrared, or laser beam, altitude sickness, etc.), respiratory diseases (cold syndrome, pneumonia, asthma, pulmonary hypertension, pulmonary thromboembolism, pulmonary thrombosis, etc.), infectious diseases (viral infectious disease by cytomegalovirus, influenza virus, herpes virus, etc., rikettsiosis, bacterial infectious diseases, etc.), toxemia (sepsis, sepsis shock, endotoxin shock, Gram-negative supsis, toxin shock syndrome, etc.), rhinolarygological diseases (Meniere's syndrome, tinnitus, dysgeusia, vertigo, disequilibrium, dysphagia, etc.), skin diseases (keloid, hemangioma, psoriasis, etc.), intradialytic hypotension, myasthenia gravis, chronic skin syndrome, and the like.

In case the physiologically active compound is a compound having angiotensin II antagonistic activity, by suppressing the action of angiotensin II for a long term, disorder and abnormality of biological and physiological functions which cause a variety of diseases accompanying adult disorder and aging can be improved, or accentuation of such disorder and abnormality can be controlled, thereby achieving primary and secondary prophylactic effects or controlling development of disease conditions caused by those diseases and symptoms. Such disorder and abnormality of biological and physiological functions include disorder and abnormality of automatic controlling capability of cerebral circulation and/or renal circulation, disorder of circulation (peripheral, cerebral, microcirculation and the like), disorder of blood-brain-barrier, insulin susceptibility deterioration, salt susceptibility deterioration, abnormal state of coagulation and fibrinolysis system, abnormal state of blood and blood cell components (accentuation of platelet

agglutinability, abnormality of erythrocyte transformation, accentuation of leukocyte agglutinating function, rise of blood viscosity, etc.), production and function accentuation of growth factor and cytokine (PDGF, VEGF, FGF, interleukin, TNF-.alpha., MCP-1, etc.), accentuation of proliferation and infiltration of inflammatory cells, accentuation of production of free radical, liposteatosis accentuation, endothelial function disorder, endothelial, cell, and organ disorder, cell morphogenesis change of edema, smooth muscle, and the like (morphogenesis to proliferation type), accentuation of production and function of vasoactive substance and thrombosis inducers (endothelin, thromboxane A2, etc.), abnormal vasoconstriction, impaired glucose tolerance, metabolic disorder (serum lipid disorder, blood sugar disorder, etc.), abnormal cell propagation, vascular rebirth (including abnormal vasa vasorum formation in adventitial coat of atherosclerosis, abnormal capillary reticular formation), and the like. Among them, the compound can be advantageously used as a primary and secondary prophylactic drug for organ disorder accompanied with a variety of diseases (e.g. cerebrovascular disorder and organ disorder following the cerebrovascular disorder, organ disorder following cardiovascular diseases, organ disorder following diabetes mellitus, organ disorder after intervention).

In the sustained-release preparation of the present invention, when the physiologically active compound is a compound having angiotensin II antagonistic activity (especially, candesartan, cilexetil, candesartan, etc.), it can be advantageously used as a prophylactic and therapeutic drug for portal hypertension. It is well known that esophagovaritosis occurs frequently during night (*Hepatology* 1994; 19: 595-601), and since the preparation of the present invention is capable of maintaining a constant blood level all day long, the preparation of the present invention is not only capable of decreasing the dosage and the number of administration as compared with those in case of a preparation for oral administration, but also expected to realize stable lowering of portal vein pressure owing to the slight fluctuation of the blood level of the drug. The above characteristics of the preparation show usefulness as a preventive drug for rupture

of varicose vein in esophagus and stomach. Further, since no symptom change is caused owing to interruption of the agent administration, it is also expected to clarify the therapeutic effect. Further, a compound having angiotensin II antagonistic activity as the physiologically active compound (especially, candesartan cilexetil, candesartan) is expected to be efficacious on the production and promotion of HGF (hepatocyte growth factor) and to attribute to liver regeneration and liver function restitution.

EXAMPLES

Example 1. Ibuprofen Dosage Form

Gelatin	5 g
Water	32.5 ml
Ibuprofen	12.5 g

The gelatin is dissolved in the water and the solution is heated at 40 - 50° C for 10 minutes. The ibuprofen is mixed with the solution and the mixture is heated for another 5 min. The mixture is then cast into molds and allowed to cool for 5 hours, after which the dosage forms are removed from the molds and packaged.

Example 2. Ibuprofen Dosage Form

Gelatin	5 g
Water	30 ml
Ibuprofen	30 g

The gelatin is dissolved in the water and the solution is heated at 40 - 50° C for 10 minutes. The ibuprofen is mixed with the solution and the mixture is heated for another 5 min. The mixture is then cast into molds and allowed to cool for 5 hours, after which the dosage forms are removed from the molds and packaged.

Example 3. NCE Dosage Form

Gelatin	2 g
Water	50 ml

NCE	3 g

The gelatin is dissolved in the water and the solution is heated at 40 - 50° C for 10 minutes. The new chemical entity (NCE) may be any pharmaceutical agent amenable to oral administration. The NCE is mixed with the solution and the mixture is heated for another 10 min. The mixture is then cast into molds and allowed to cool for 3 hours, after which the dosage forms are removed from the molds and packaged.

Example 4. NCE Dosage Form

Gelatin	2 g
Water	50 ml
NCE	20 g

The gelatin is dissolved in the water and the solution is heated at 40 - 50° C for 10 minutes. The NCE is mixed with the solution and the mixture is heated for another 10 min. The mixture is then cast into molds and allowed to cool for 3 hours, after which the dosage forms are removed from the molds and packaged.

I claim::

1. A solid dosage form that facilitates swallowing comprising a gelatinous hydrated polymeric matrix, one or more active ingredients and optionally one or more excipients.

2. The solid dosage form of Claim 1 wherein the polymeric matrix is a gel.

3. The dosage form of Claim 2 wherein the hydrated gel is hydrated type A gelatin with a bloom value from 0 to 250

4. The dosage form of Claim 2 wherein the hydrated gel is hydrated type B gelatin with a bloom value from 0 to 250.

5. The dosage form of Claim 1 wherein the polymeric matrix is an easily hydrated food grade or GRAS polymer.

6. The dosage form of Claim 5 wherein the polymeric matrix is hydroxypropyl cellulose.

7. The dosage form of Claim 5 wherein the polymeric matrix is hydroxymethyl cellulose.

8. The dosage form of Claim 5 wherein the polymeric matrix is polyethylene oxide.

9. The dosage form of Claim 5 wherein the polymeric matrix is pectin.

10. The dosage form of Claim 5 wherein the polymeric matrix is hyaluronic acid.

11. The dosage form of Claim 5 wherein the polymeric matrix is agar.

12. The dosage form of Claim 1 wherein an optional excipient is a flavoring agent.

13. The dosage form of Claim 1 wherein an optional excipient is a salivation inducing agent.

14. A method of administering a pharmaceutical agent to a patient who has a swallowing problem associated with dysphagia.

15. The dosage form of Claim 1 wherein at least one of the active ingredients is a therapeutic chemical, a mineral or vitamin.

16. The dosage form of Claim 15 wherein the therapeutic chemical is a mineral or vitamin are selected from the group comprising: ascorbic acid (vitamin C), calcium carbonate, dl-alpha-tocopherol acetate (vitamin E), magnesium oxide, ferrous fumarate, niacinamide, zinc oxide, calcium pantothenate, pyridoxine HCl (vitamin B6), riboflavin (vitamin B2), thiamin mononitrate (vitamin B1), cupric oxide, vitamin A acetate, vitamin D, beta-carotene, chromium chloride, biotin, folic acid, potassium iodide, sodium molybdate, sodium selenate, phytonadione (vitamin K1), sodium metavandate, nickelous sulfate, sodium aluminum silicate, cyanocobalamin (vitamin B12), stannous chloride.

17. The dosage form of Claim 1 wherein at least one of the active ingredients is an extract from a plant.

18. The dosage form of Claim 17 wherein the plant is selected from the group comprising: echinacea, Ginseng root extract, Ginkgo Biloba, St. Johns Wort.

19. The dosage form of Claim 1 wherein at least one of the active ingredients is a non-prescription drug.

20. The dosage form of Claim 19 wherein the non-prescription drug is selected from the group comprising: acetaminophen, captopril, diltiazem, nifedipine, dicyclomine, alprazolam, amitriptyline, clomipramine, propranolol hydrochloride, labetalol, allopurinol, metformin, atenolol, potassium chloride, lithium, levothyroxine sodium, Ibuprofen, estrogen, and acetyl salicylic acid.

21. The dosage form of Claim 1 wherein at least one of the active ingredients is a prescription drug.

22. The dosage form of Claim 21 wherein the prescription drug has indications is selected from the group comprising: Anemia, Anesthesia, Angina, Angioplasty, Antibiotic, Anti-coagulant, Anti-fungal, Arrhythmia, Cancer, Contraceptive, Cystic Crohn's Disease, Fibrosis, Growth hormone deficiency, Hemophilia, Heart attack, Hepatitis, Macular degeneration, Meningococcal meningitis, Multiple Sclerosis, Pulmonary hypertension, Rheumatoid Arthritis and Thrombosis.

23. A variably thickened therapeutic agent composition suitable for oral administration to a subject comprising a uniformly distributed physiologically active agent, water and at least one hydrogel-forming component, wherein the composition does not release the physiologically active agent in the mouth and that facilitates swallowing.

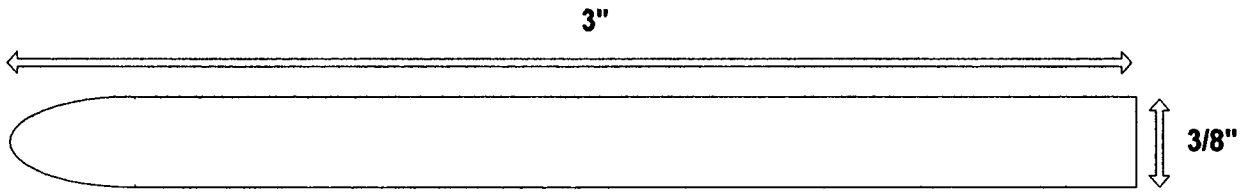

Fig. 1

Fig. 2